

Diagnostics For All

By DANIEL GORELICK

Nonprofit company's unique business model could revolutionize the way poor patients are tested for disease.

Thanks to an international group of scientists, engineers, physicians and business people, a nonprofit company with a novel business model is poised to change the way patient health is monitored in the developing world.

The company, Diagnostics For All, was founded by Harvard University professor George Whitesides and Hayat Sindi, a scientist from Saudi Arabia, based on technology developed in Whitesides' laboratory.

Using inexpensive and readily available paper and adhesive tape, Whitesides and colleagues developed a small, disposable device that can be used to test bodily fluids for signs of illness.

Sindi, the driving force behind commercializing the technology, assembled a team of Harvard and Massachusetts

Institute of Technology students and scientists to write a business plan, which won first place in two prestigious competitions: the Harvard Business School Business Plan Competition and the MIT \$100K Entrepreneurship Competition. Diagnostics For All is the first nonprofit company to win the MIT competition.

Team members include Sindi, scientist Carol Waghorne and Iranian American bioengineer Roozbeh Ghaffari; physicians Gilbert Tang, from Canada, and Indian American Krishna Yeshwant; and businessman Jon Puz.

"U.S. universities expect students and professors to achieve great things, but they also understand that to achieve truly great things you often need to take calculated risks that don't always end in suc-

cess. To encourage people to take calculated risks U.S. universities offer grants, develop competitions like the MIT \$100K and HBS business plan competitions, they provide space for people to work, enable access to innovators from academia and from industry, and offer ways to take ideas that seem viable from the business plan stage to actual implementation," says Yeshwant, who is in the final year of a combined MD/MBA five-year degree program at Harvard.

To make the test kits available in the developing world quickly, the leaders of Diagnostics For All (<http://www.dfadx.org/>) passed up potentially lucrative royalties and made the company nonprofit.

"It is hard to treat people who are outside of conventional medical settings," says

James Barber, executive director of Diagnostics For All, who was hired to run the company after the Harvard and MIT competitions. He says the company's technology offers a "really compelling" solution for the 60 percent of people in the developing world who live in rural areas and do not have access to medical facilities.

Using the technology involves placing a drop of a patient's blood, sweat or urine on specially treated paper. The fluid is then conveyed to distinct zones that change color to determine the presence of certain proteins that can, in turn, indicate certain renal diseases and metabolic disorders.

The images of the color changes can be read at the point of care or photographed with a cell phone and sent to an off-site lab where they can be analyzed by a specialist, who can then send back a result.

"A couple of my friends told me about the technology during my first year of business school and said they needed help putting a business plan together. Having had a couple of entrepreneurial experiences in software before and a lot of interest in medical technology I thought it would be worth learning more about what they were working on....Someone had to make these devices for the sake of all the people who currently have no access to diagnostics," says Yeshwant, who grew up in Chicago, Illinois. His parents moved to the United States from Andhra Pradesh in the 1970s.

An urgent problem

Sindi's goal is to make the diagnostic technology quickly available to the developing world—the main reason for setting up Diagnostics For All as a nonprofit rather than a for-profit company.

As a for-profit company, Diagnostics For All would have to defer devoting resources to manufacturing and delivering diagnostic kits to developing countries until the company was profitable, a process that might take seven or eight years, according to Sindi.



Far left: A sample device detecting glucose (two left areas) and protein (two right areas) in artificial urine.

Above: Carol Waghorne (from left), Krishna Yeshwant, Gilbert Tang, Hayat Sindi, Roozbeh Ghaffari and Jon Puz.

The team writing the Diagnostics For All business plan agreed the problem of inadequate medical diagnostics needs to be addressed now, according to Tang, a resident in cardiac surgery at the University of Toronto. He worked on the plan while a student at Harvard Business School.

Supply chain and distribution issues are "really different" in the for-profit and nonprofit markets, says Tang. For example, diagnostic test kits in sub-Saharan Africa would be subject to high levels of heat and humidity, conditions that are not a factor for the for-profit markets in the United States and Western Europe.

An unusual business model

Nonprofit companies typically rely on donations and grants from philanthropic organizations. Diagnostics For All's business plan is unusual in that it envisions using patent royalties as a sustainable income source.

In a typical arrangement, a for-profit company would pay a royalty fee to Harvard University to license the diagnostic technology. Whitesides and his colleagues, the scientists who invented the technology, would receive a percentage of the royalties.

Diagnostics For All, however, is able to license Whitesides' technology without charge. In an agreement negotiated with Harvard University, if a for-profit company wants to license the technology, Diagnostics For All can negotiate royalty fees on behalf of itself and Harvard—Harvard would receive a share of the royalties, and Diagnostics For All's share would be invested in itself.

Sindi, Tang, Whitesides and others will forgo their share of potentially lucrative

royalties because, as Tang explains, the global health consequences trump the loss of financial rewards. "This technology could completely transform diagnostics" in the developing world—present methods are "archaic" in comparison.

Some question whether the nonprofit model will motivate employees in the absence of financial incentives.

Barber says that the profit motive does not guarantee productivity. Profit motivation is a disciplining tool, but there are many ineffective, unproductive for-profit companies—for example, the big three U.S. automobile companies. Determination to succeed is a powerful motivator.

Hiring talented employees will also not be a problem, Barber says. "We pay a reasonable wage, and people are excited. They want the personal satisfaction that comes from making a difference."

Diagnostics For All is now working to adapt Whitesides' technology to test for levels of proteins in the blood that are a sign of liver failure, a byproduct of some medications used to treat disease. Barber hopes to have working prototypes in 2009 and to begin pilot manufacturing programs and field tests in 2010.

In the future, Barber imagines using the technology to develop tests for kidney function and diseases such as tuberculosis, HIV/AIDS and malaria.

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